UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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ABBOTT LABORATORIES, ABBOTT DIABETES CARE INC., and ABBOTT DIABETES CARE SALES CORPORATION,

Plaintiffs,

-against-

ADELPHIA SUPPLY USA; YUDAH NEUMAN A/K/A LENNY NEUMAN; REUVEN SOBEL A/K/A CHAIM SOBEL; MOSES NEUMAN; SHMUEL LEZELL; SAVE RITE MEDICAL.COM: LLC; MARC KAPLAN; MATRIX DISTRIBUTORS, INC.; CHRISTOPHER BENEVENT; SETH GRUMET; H&H WHOLESALE SERVICES, INC.; HOWARD GOLDMAN; LORI GOLDMAN; PAPOUTSANIS USA, LLC D/B/A VIP INTERNATIONAL – DROGARIS; GEORGE DROGARIS; OSD CAPITAL, INC. F/K/A FARNES ENTERPRISES CORPORATION; OVERSTOCKDRUGSTORE.COM LLC D/B/A/ SIMPLEMED SUPPLY; RICK EVENSON; KEVIN PLUMB; BUDGET HEALTH CORPORATION D/B/A BUDGET DRUGS PHARMACY; JOHN FANDETTI; ROBERT NEWMYER; MARIA FANDETTI; LORI BLUE; ANTHONY MEOLA; MARK D. HENKIN; DREAM CEREAL INC. D/B/A DIABETESSUPPLIES4LESS.COM; DOUGLAS HAUCK; BERKELEY DRUGS INC.; MAJID HAMEED; EUGENE HA; CAREWAY PHARMACY INC.; ANATOLIY FAIN; HARRICO-GALLER DRUG CORPORATION; JOHN GALLAGHER; HABER J&N INC. D/B/A THE MODERN CHEMIST; NAOMI HABER; JERRY HABER; NORSTRAND PHARMACY, LLC D/B/A VANDERVEER PHARMACY; SARATHCHANDRA ADUSUMALLI; HEMAGIRI GAYAM; LEV RX CORP. D/B/A KIRA'S PHARMACY; KIRA LEVKOUSKAYA; ELIYAHUS PHARMACY, INC.; ILIAS

15 Civ. _____

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' REQUEST FOR ORDER TO SHOW CAUSE FOR PRELIMINARY INJUNCTION WITH TEMPORARY RESTRAINING ORDER

MLABASATI; GLOBAL CARE PHARMACY, INC.; D.K.Y. ENTERPRISES, INC. D/B/A 8TH AVENUE PHARMACY; KIM PING JIM; TGIS PHARMACY, INC. D/B/A SUNRISE FAMILY PHARMACY; SAJID JAVED; BAY PHARMACY INC.; IRENE PIKER; B & T MARLBORO PHARMACY, INC.; ANATOLY GOROKHOVSKY; LARKE DRUGS, INC. D/B/A 110 PHARMACY & SURGICAL; PRASAD VENIGALLA; LA RUCHE PHARMACY, INC.; SUNIL B. PATEL; ESTATES PHARMACY, INC.; MOHAMMED NURUDDIN; and JOHN DOES 1-10,

Defendants.

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Abbott Laboratories, Abbott Diabetes Care Inc., and Abbott Diabetes Care Sales Corporation (collectively, "Abbott") submit this memorandum of law in support of their application for injunctive relief barring Defendants from illegally selling blood glucose test strips that infringe Abbott's trademarks and violate state unfair competition statutes.

I. PRELIMINARY STATEMENT

Abbott makes and sells FreeStyle® and FreeStyle Lite® (collectively, "FreeStyle") brand blood glucose test strips, which millions of individuals with diabetes use on a daily basis to monitor their blood sugar and help them control their disease. Unfortunately, Abbott recently discovered that Defendants and others like them are illegally distributing and selling foreign versions of FreeStyle test strips that are not intended for sale in the United States and whose packaging and labeling violate U.S. law in myriad ways.

By selling these foreign products in the United States, Defendants are engaged in the sale of misbranded medical devices—a federal crime. Because consumers have no idea that the products they are buying are actually illegally diverted international products, Defendants are also violating the federal Lanham Act and state unfair competition law. Moreover, the Defendants profit from these diverted products by falsely representing them as U.S. products and by seeking and receiving undeserved reimbursement from insurers and indirect rebates from Abbott based on these fraudulent misrepresentations. Most importantly, Defendants' numerous violations of U.S. labeling requirements have the potential to confuse or negatively impact diabetes patients who rely on FreeStyle test strips and who need clear, understandable, and lawful information about how to use these products properly. The distribution and sale of these misbranded, confusing, and potentially risky products should therefore be enjoined immediately.

Blood glucose test strips, and the blood glucose monitoring systems of which they are part, are regulated medical devices that cannot be distributed or sold in the United States without prior clearance by the Food and Drug Administration ("FDA"). The FDA imposes a variety of highly specific requirements for the labels and packaging of blood glucose test strips. The labels must provide careful and evidence-supported directions for use, describing, for example, the sites from which blood can be drawn and the units of measurement to be used. They must provide a clear and effective means of contacting the company by phone with questions or quality concerns; unlike the customer service phone numbers on ordinary consumer products, these numbers are used to provide vital instructions on the use of the devices and to monitor their quality, including the potential need for recalls. FreeStyle labels identify each product precisely with individualized codes that are used to track quality and to process the insurance payments and rebates by which virtually every FreeStyle test strip sold in the United States is paid for.

The Defendants in this case are actively engaged in the domestic sale of diverted international boxes of FreeStyle test strips. Because these products are not intended for sale in the United States, they are not cleared by the FDA and they violate U.S. labeling requirements in multiple ways detailed below. As just one example, the test strip packages Defendants sell include claims about the sites from which blood samples can be collected that have been *specifically rejected* by the FDA, and therefore cannot, and do not, appear on the labels of Abbott's U.S. products.

The labels on the illegally diverted test strips sold by Defendants lack the valid U.S. customer service number that plays such an important role in Abbott's quality control. These labels do not inform consumers of this diverted product about how to contact Abbott in the event of a quality or usage issue. Furthermore, because the illegally diverted test strips are being sold

in the United States rather than in the country where they were intended for sale, any recall notices issued for the products may not reach these U.S. consumers and these consumers will continue to use recalled products.

The illegally diverted test strips also lack the U.S. product codes that allow for valid insurance reimbursement. Because over 95% of FreeStyle test strips are paid for by insurers, no one can profit from selling FreeStyle products without access to insurance. To access that insurance, Defendants and the pharmacies that stock these diverted international products are fraudulently attributing U.S. codes to the products and obtaining unwarranted reimbursements—and inflated profits—on that basis. Notably, every penny of the gains Defendants obtain by their fraud lines their pockets. Consumers see no economic benefit, as they pay the same amount for illegally diverted test strips as they would for legitimate U.S. products. Defendants' illegal and fraudulent activity must be enjoined.

II. FACTS

A. Abbott Owns the Well-Known and Invaluable FreeStyle Brand and FreeStyle Marks.

Abbott makes and sells the well-known, high-quality FreeStyle brand of blood glucose test strips. FreeStyle test strips are crucial medical devices for more than 2 million Americans with diabetes who use FreeStyle test strips and meters daily to monitor their blood sugar and manage their diabetes.

To use the FreeStyle test strips and meter, a user first places a test strip into a meter. Next, the patient obtains a tiny blood sample from his or her finger tip, upper arm, or palm using a lancing device. The user then applies the blood sample to the test strip. Seconds later, the glucose reading is displayed on the meter's digital screen. Based on this reading, patients make

decisions concerning when to take insulin and how to adjust their diets to ensure a healthy blood-glucose level.

Abbott is the owner of the federal trademark registrations appearing on the packaging for FreeStyle test strips, including: FREESTYLE, Reg. No. 3,111,863; FREESTYLE LITE, Reg. No. 3,488,499;  (the FreeStyle Butterfly Design mark), Reg. No. 4,210,535; ABBOTT (Reg. Nos. 3,724,557; 3,842,268; 3,842,269; 4,023,123); and  (Reg. Nos. 1,542,129) (collectively, the "FreeStyle Marks"). Declaration of Geoffrey Potter dated October 8, 2015 ("Potter Decl.") ¶ 2.

The sale of FreeStyle test strips has been tremendously successful in part due to Abbott's marketing and promotion of the FreeStyle brand throughout the country. Abbott distributes and sells over 600 million FreeStyle test strips every year in the United States alone and has sold billions of FreeStyle test strips for over $1 billion in revenue in the United States over the past five years. Declaration of Todd Nelson dated October 6, 2015 ("Nelson Decl.") ¶ 4. FreeStyle test strips are sold in pharmacies throughout the United States and world. The FreeStyle brand is recognized throughout the world as a high-quality, reliable blood glucose test strip manufactured and distributed by Abbott. *Id.* ¶ 19. Because the purchasing public has come to know this, the FreeStyle Marks and the goodwill associated with them are of inestimable value to Abbott. *Id.* ¶ 20.

B. Due to Regulatory Requirements, the Packaging and Instructions for FreeStyle Test Strips Differ Dramatically Between the United States and the Rest of the World.

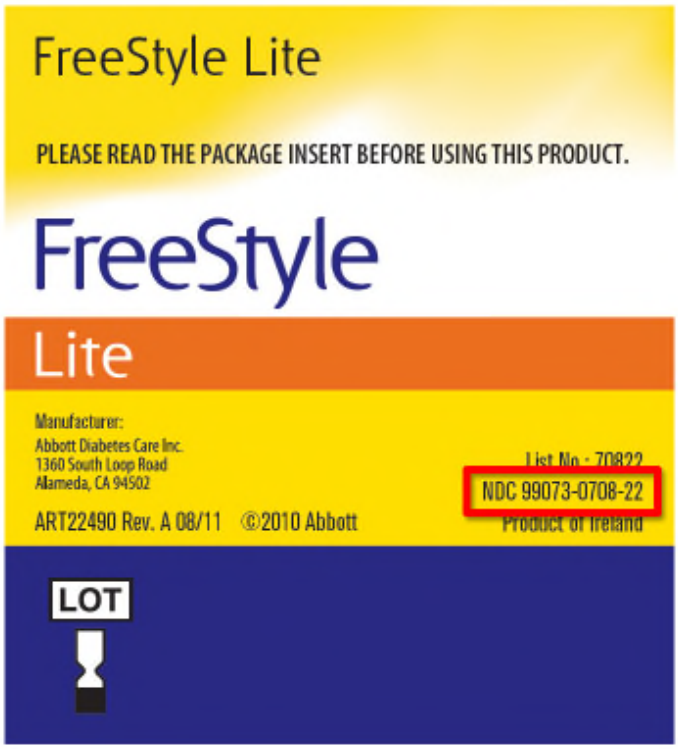
Public health agencies in the United States and abroad actively regulate the sale of blood glucose test strips, and in particular, what must be included and excluded from their labels and

packaging. In the United States, the FDA has cleared the distribution and use of FreeStyle test strips under very particular, stringent package labeling and usage requirements. International regulatory agencies also have very particular, but different, regulatory requirements. Therefore, the FreeStyle test strips Abbott sells in the United States have different packaging and instructions than international FreeStyle test strips. FreeStyle test strips intended for distribution outside the United States have not been cleared by the FDA for distribution in the United States.

1. Different use of NDC numbers

Every retail box of FreeStyle test strips that is cleared for sale in the United States bears a specific National Drug Code ("NDC") number, which is a ten-digit number that incorporates Abbott's assigned product and package codes. Declaration of Arul Sterlin dated October 5, 2015 ("Sterlin Decl.") ¶ 6. Abbott uses the NDC number to track U.S. retail sales and to ensure the test strips are appropriate for reimbursements and rebates. The NDC number appears both on the front and bottom of U.S. boxes. *Id.* ¶¶ 6-7. Below is an image of the outer packaging of a U.S. retail box of FreeStyle Lite test strips, with the NDC code highlighted:

Front image of U.S. retail box of FreeStyle Lite test strips



Bottom image of U.S. retail box of FreeStyle Lite test strips

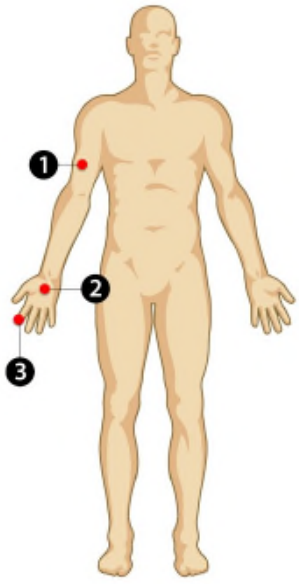
FreeStyle test strips that are intended for sale outside the United States do not have an NDC number. *Id.* ¶ 6-7.

2. Different indicated test sites

When performing a blood glucose test, the patient must obtain a blood drop from a "test site" on his or her body. Many patients test their glucose levels multiple times per day and

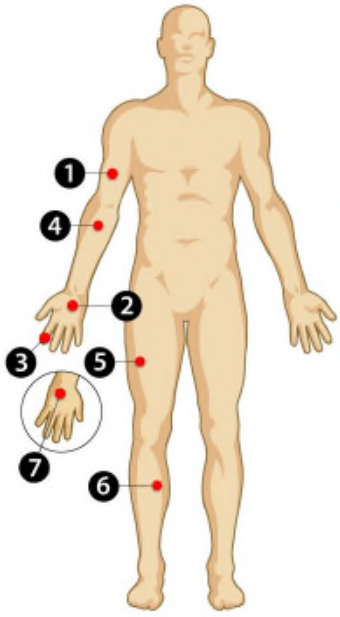
would like to be able to use a number of different test sites. Sterlin Decl. ¶ 10. U.S. and international FreeStyle test strips feature different approved test sites.

In 2009, Abbott sought clearance from the FDA to indicate testing at seven sites: finger; upper arm; palm; back of hand; forearm; calf; and thigh. *Id.* ¶ 11. In support of this application, Abbott submitted data of testing at all seven sites. *Id.* In evaluating Abbott's data, however, the FDA determined that the back of hand, forearm, calf, and thigh test sites did not meet the FDA's criteria. Therefore, the FDA only cleared three test sites for FreeStyle test strips: finger; upper arm; and palm. *Id.*



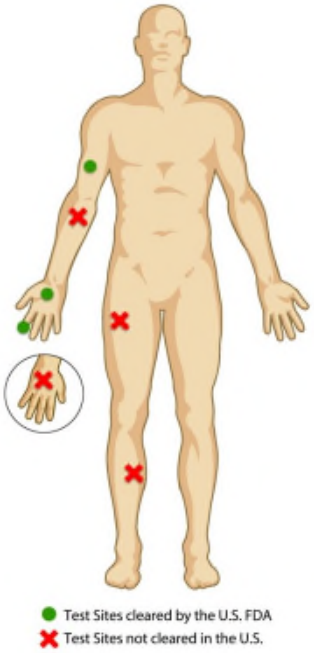
Test Sites cleared by the U.S. FDA

Outside the United States, however, FreeStyle test strips are approved for testing at additional sites, including the back of hand, forearm, calf, and thigh. *Id.* ¶ 12. Accordingly, international FreeStyle test strips are packaged with guidance and instructions for testing at a broader range of sites than U.S. FreeStyle test strips.



International Test Sites

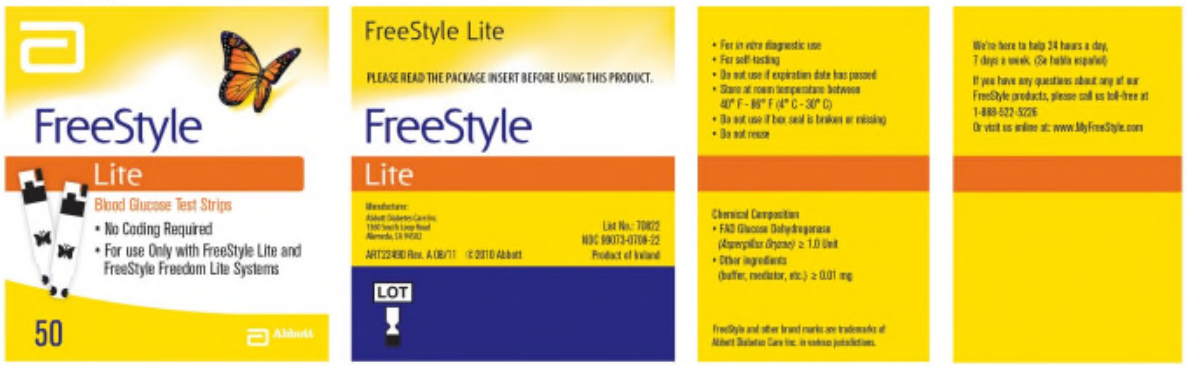
Any international FreeStyle test strips that are diverted to and distributed in the United States would indicate testing sites that are not cleared by—and were *explicitly rejected by*—the FDA in the United States. Thus, U.S. consumers who receive an international package of FreeStyle test strips would receive instructions that they may test at sites which the FDA has not cleared. *Id.* Those instructions violate the FDA's clearances and render these products misbranded when offered for sale in the United States.



3. Different languages

The exterior package labeling of every box of FreeStyle test strips contains very important information concerning, among other things, usage and handling. Every box contains an instructional insert, which also provides a substantial amount of vital information, including directions and warnings concerning the use of FreeStyle test strips. For obvious reasons, the language or languages that the package comes in varies depending on the intended country or region of distribution. *Id.* ¶ 15. The figure below provides just one example of the language differences present on a box of U.S. and international FreeStyle test strips:

U.S. version:

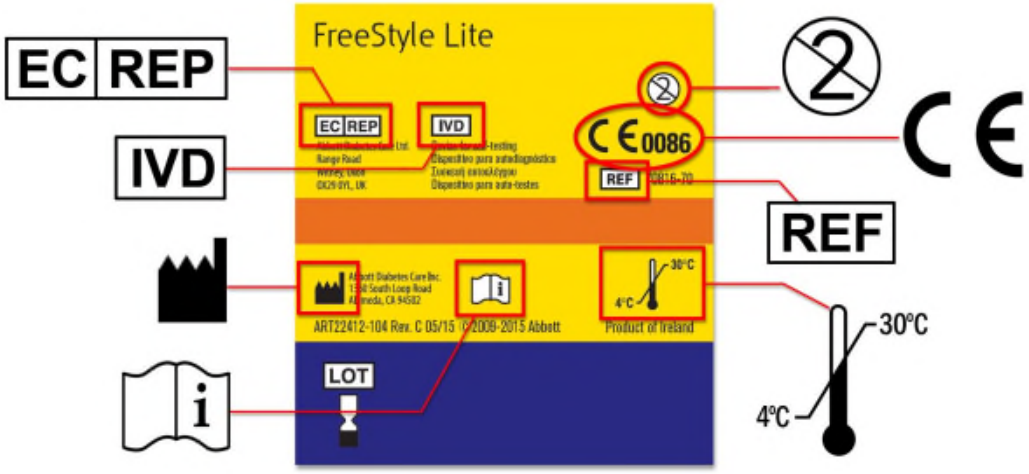


Middle East version:

As required by the FDA, all FreeStyle test strips intended for distribution and sale in the United States are accompanied by instructional inserts written in English. *Id.* ¶ 16. They also bear a second language, Spanish. FreeStyle test strips that are manufactured for sale internationally contain instructional inserts written in various languages that do not include English or Spanish. *Id.* For instance, FreeStyle test strips that are packaged for sale in Germany, Switzerland, France, Belgium, and the Netherlands do not provide any instructions in English or Spanish. *Id.*

4. Different use of symbols

International FreeStyle test strips are packaged in boxes and with instructions that bear various symbols concerning, among other things, the manufacturer, expiration date, and storage temperature limitations. *Id.* ¶ 19.



In the United States, by contrast, the FDA does not generally approve the use of symbols on packaging for home-use products unless the symbols are accompanied by adequate explanatory text. *Id.* ¶ 18.

5. Different units of measurement

The FDA requires that U.S. products use specific units of measurement, including milligrams and deciliters. *Id.* ¶ 20. However, various regions around the world use other units of measurement, including millimoles. *Id.* The FDA does not permit the use of other units of measurement because it can confuse U.S. consumers. *Id.* While the packaging and instructional inserts for many international regions incorporate both milligram and millimole measurements, the instructional insert for FreeStyle test strips packaged for sale in Canada exclusively reference millimoles, and do not incorporate or offer alternative measurements using units required by the FDA. *Id.* & Sterlin Ex. 16.

In addition, the FDA also requires that U.S. products use Fahrenheit as the unit of measurement for temperature. *Id.* ¶ 21. The side of every U.S. box of FreeStyle test strips includes the following warning: "Store at room temperature between 40° F - 86° F (4° C - 30° C)." *Id.* International FreeStyle test strips do not provide this written warning anywhere on the outer box, but instead rely on a symbol, which lists storage requirements in Celsius only, and offers no explanatory text.

U.S. version

- For *in vitro* diagnostic use
- For self-testing
- Do not use if expiration date has passed
- Store at room temperature between 40° F - 86° F (4° C - 30° C)
- Do not use if box seal is broken or missing
- Do not reuse

Chemical Composition
- FAD Glucose Dehydrogenase *(Aspergillus Oryzae)* ≥ 1.0 Unit
- Other ingredients (buffer, mediator, etc.) ≥ 0.01 mg

FreeStyle and other brand marks are trademarks of Abbott Diabetes Care Inc. in various jurisdictions.

India version

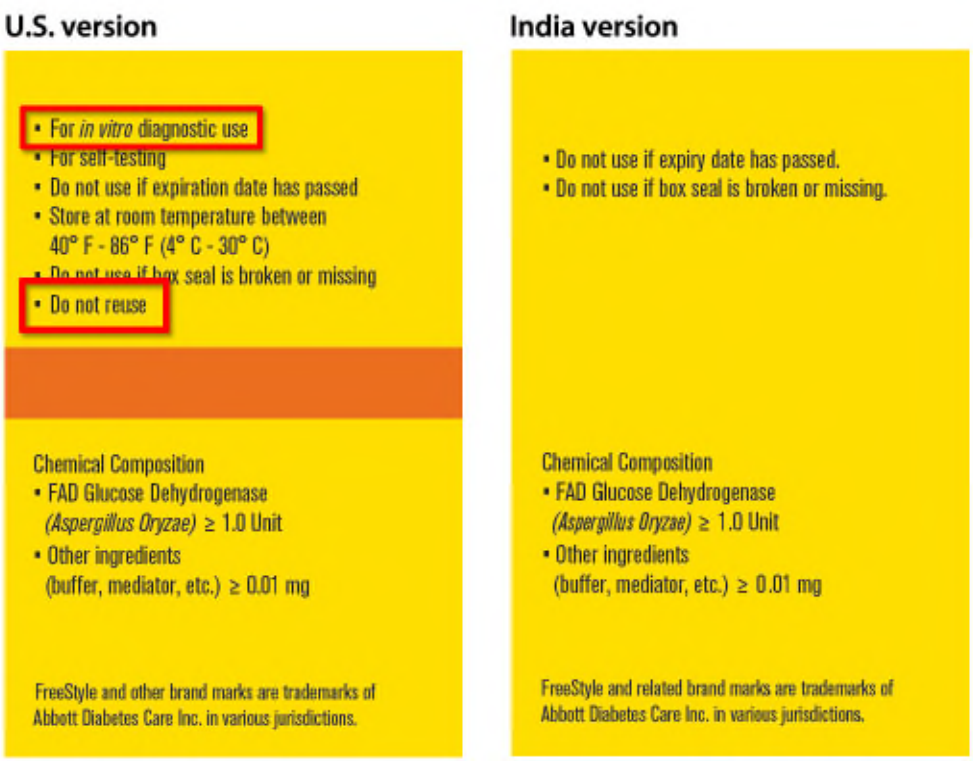
- Do not use if expiry date has passed.
- Do not use if box seal is broken or missing.

Chemical Composition
- FAD Glucose Dehydrogenase *(Aspergillus Oryzae)* ≥ 1.0 Unit
- Other ingredients (buffer, mediator, etc.) ≥ 0.01 mg

FreeStyle and related brand marks are trademarks of Abbott Diabetes Care Inc. in various jurisdictions.

6. Different warnings

The outer box of international FreeStyle test strips also do not provide several written warnings and instructions featured on U.S. boxes, including "Do not reuse" and "For *in vitro* diagnostic use." *Id.* ¶ 23.



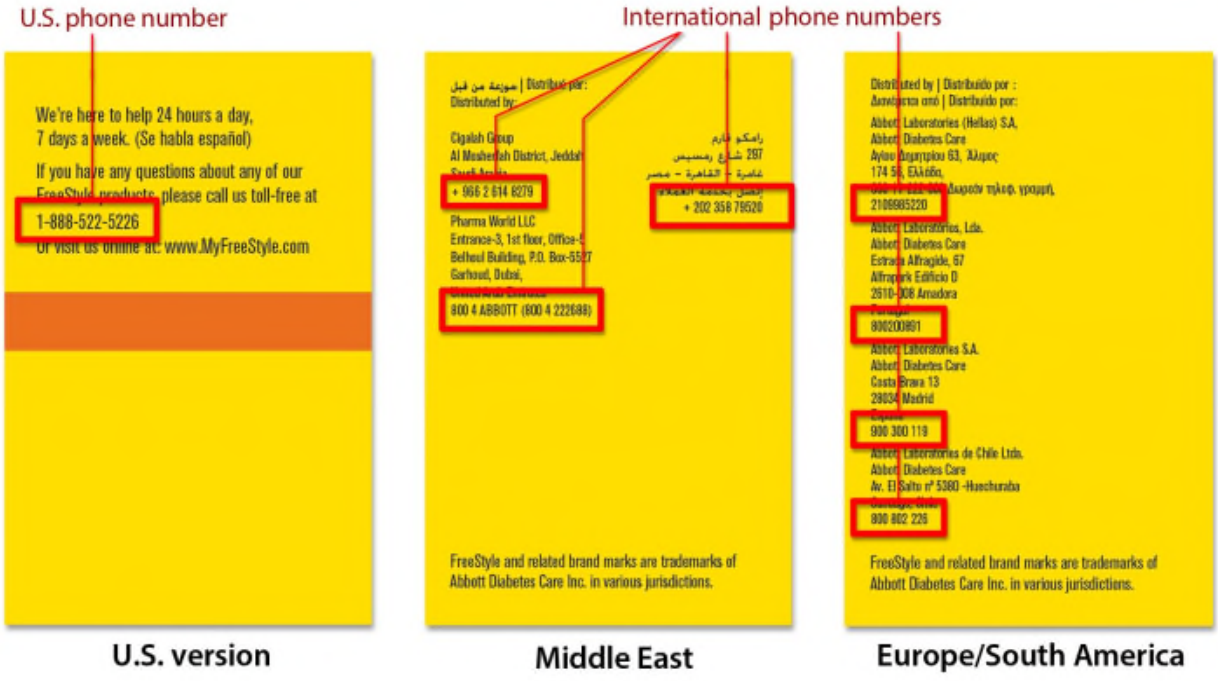
C. Abbott Makes Extensive Efforts to Ensure Consistent Quality and Educate Consumers About Proper Use.

Because blood glucose test strips are life-saving medical devices that patients rely on for their health and well-being, Abbott devotes a substantial amount of effort and resources to ensure product quality and consumer safety. In addition to the pre-market measures Abbott takes, after FreeStyle test strips are distributed, Abbott continues to monitor the market, receiving consumer inquiries, tracking and investigating complaints and market issues, and performing any necessary field actions, including making targeted recalls and initiating legal proceedings. Declaration of Jeffrey Kelley dated October 2, 2015 ("Kelley Decl.") ¶¶ 3, 6; Declaration of Karen P. Gillis dated October 2, 2015 ("Gillis Decl.") ¶¶ 3-5.

FreeStyle test strips are manufactured in Ireland with a specific stock keeping unit ("SKU") and lot number. Kelley Decl. ¶¶ 4-5. Each lot is only manufactured for sale in a specific country (e.g., the United States) or region (e.g., the Middle East). *Id.* Abbott uses the

SKU and lot number to track where the test strips are shipped and then to monitor them should any safety or quality issues arise. *Id.*

Every box of FreeStyle test strips provides a phone number for consumers to call with any inquiries, complaints, or issues. Sterlin Decl. ¶ 14. The phone number is specific to the country where the test strips are shipped for sale. In the United States, the toll-free phone number is 1-888-522-5226. *Id.* Below are images of packaging for retail boxes of FreeStyle Lite test strips in different parts of the world, with the different phone numbers highlighted.



Abbott's call center for U.S. consumers plays a vital role in receiving consumer feedback and inquiries about FreeStyle test strips. Gillis Decl. ¶¶ 4-5. It also provides consumers with important instructions about how to properly test their blood glucose levels and information related to quality issues and recalls. *Id.* ¶ 8. U.S. call center personnel are trained and equipped to answer questions about FreeStyle test strips intended for sale in the United States. *Id.* Calls are logged in Abbott's call registration system, with a perception code, case number, and other

details provided by the caller. *Id.* ¶ 5. Abbott tracks consumer calls and analyzes them for larger issues and trends. Kelley Decl. ¶ 6. Depending on the nature and severity of the consumer inquiry—that is, if it involves a safety issues or potential product defect—Abbott will follow-up with the consumer or investigate the issue. *Id.*

When a recall is warranted, Abbott identifies the countries to which it shipped the affected test strips and provides, among other things, a direct notification to all consignees for the affected lot number, including distributors, retailers, pharmacies, and, where possible, consumers and health care professionals. *Id.* ¶ 7. Abbott informs them of the affected SKU and lot number, the issue, and any further action that may be necessary. *Id.* Abbott's efforts in relation to a recall are keyed to relevant regulatory requirements and guidance. *Id.* ¶ 6. When FreeStyle test strips are diverted from their authorized distribution channel, it undermines and impedes Abbott's efforts to maintain quality control and ensure consumer well-being. *Id.* ¶¶ 9-10.

D. Defendants Are Selling Diverted International FreeStyle Test Strips in the United States.

As part of Abbott's quality control measures, Abbott investigates, among other things, the diversion of its products. Declaration of Thomas J. Kneir dated October 8, 2015 ("Kneir Decl.") ¶ 3. Diverted (or "gray market") product is product that was manufactured for sale in a specific market—here, outside the United States—and is then sold into a different (unauthorized) market—the United States. When Abbott discovers product in the United States that is not suitable or approved for sale, Abbott notifies relevant federal and local law-enforcement authorities. *Id.* ¶ 7, 9.

Abbott recently discovered a multi-leveled conspiracy to import and sell large volumes of diverted international FreeStyle test strips in the United States. *Id.* ¶¶ 5-9. The companies and

individuals that are distributing diverted test strips to pharmacies are at the center of this conspiracy. To investigate the distributors of these diverted FreeStyle test strips, Abbott's Director of Product Security, Thomas Kneir, arranged for and made purchases from them. On June 8, 2015, Abbott purchased 12 cartons (1 case) of diverted 50-count FreeStyle Lite test strips from **Adelphia Supply USA** ("Adelphia"), a company in Brooklyn, New York.[1] In just the last few weeks, Abbott purchased diverted international FreeStyle test strips from each of the following distributors (the "Distributor Defendants"):

- **Save Rite Medical.com LLC**, Brooklyn, New York
- **Matrix Distributors, Inc.** ("Matrix"), East Brunswick, New Jersey
- **H&H Wholesale Services, Inc.** ("H&H"), Troy, Michigan
- **Papoutsanis USA, LLC, d/b/a VIP International - Drogaris**, Staten Island, New York
- **Overstockdrugstore.com LLC, d/b/a SimpleMed Supply**, Bluffdale, Utah
- **Budget Health Corporation d/b/a Budget Drugs Pharmacy**, Hallandale, Florida
- **Dream Cereal Inc. d/b/a/ Diabetessupplies4less.com**, Boynton Beach, Florida

All of these purchases were shipped to and received in the Eastern District of New York. *Id.* ¶¶ 11-18. Adelphia, for one, also sent blast faxes advertising that it offers international boxes of FreeStyle test strips. *Id.* ¶ 8.

The Distributor Defendants sell the diverted FreeStyle test strips primarily to independent pharmacies throughout the United States. These pharmacies sell the diverted FreeStyle test strips

[1] In early 2014, Abbott uncovered Adelphia distributing diverted FreeStyle test strips in the United States. Abbott immediately notified the FDA Office of Criminal Investigations ("OCI"), and the matter was assigned to the FDA OCI field office in New York. Kneir Decl. ¶ 7.

to unsuspecting consumers, almost all of whom purchase with insurance. In September and October 2015, Abbott bought 50-count boxes of diverted FreeStyle test strips from the following independent pharmacies, all of which are located in Brooklyn, New York: **Berkeley Drugs**; **Careway Pharmacy Inc.**; **Harrico Galler Drug**; **The Modern Chemist**; **Vanderveer Pharmacy**; **Kira's Pharmacy**; **Eliyahus Pharmacy**; **Global Care Pharmacy**; **8th Avenue Pharmacy**; **Sunrise Family Pharmacy**; **Bay Pharmacy**; **B T Marlboro Pharmacy; 110 Pharmacy & Surgical; Laruche Pharmacy;** and **Estates Pharmacy**[2] (collectively, the "Pharmacy Defendants"). These are just a few of the pharmacies that are buying and selling diverted international FreeStyle test strips in the United States. Kneir Decl. ¶¶ 21-32.

Several of the Distributor Defendants have previously been sued for—and permanently enjoined from—similar conduct with respect to a different brand of blood glucose test strips.

- H&H was sued by a competing blood glucose test strip manufacturer, LifeScan, Inc., which accused H&H of purchasing and selling counterfeit boxes of LifeScan test strips. Potter Decl. Ex. 3. In that case, H&H acknowledged that it purchased more than 20,000 boxes of LifeScan test strips from abroad, and Chief Magistrate Judge Gold concluded that all of those boxes were counterfeit. Potter Decl. Ex. 4 at 18, 40-41. LifeScan sued H&H again in 2014, this time in Massachusetts federal court, making allegations similar to those that Abbott makes here: that H&H's sale of diverted international test strips within the United States was illegal. Potter Decl. Ex. 5. LifeScan and H&H settled the New York counterfeiting case and the Massachusetts illegal diversion case, with H&H paying LifeScan $2 million. Potter Decl. Ex. 6. The judgment signed by Judge Townes permanently enjoined H&H from selling diverted international LifeScan test strips. *Id.* After this settlement, LifeScan agreed to dismiss its Massachusetts lawsuit against H&H. Potter Decl. Ex. 7.

- LifeScan also sued Matrix, accusing it of selling counterfeit LifeScan test strips. Potter Decl. Ex. 8. In September 2015, Judge Townes signed an order permanently enjoining Matrix from dealing in diverted international LifeScan test strips. Potter Decl. Ex. 9.

- Adelphia has been sued on multiple occasions for the unlawful sale and distribution of diverted and/or counterfeit blood glucose test strips. In 2014,

[2] Estates Pharmacy is located in Jamaica, Queens, New York.

Lifescan brought suit against Adelphia and its owner, Yudah Neuman, alleging that Adelphia had intentionally imported foreign, gray-market versions LifeScan test strips into the United States. Potter Decl. Ex. 10. The complaint alleged gray-market diversion going as far back as 2011, when FDA had first seized a shipment of counterfeit test strips intended for Adelphia, and further alleged that Adelphia had also breached a 2013 settlement agreement in which it agreed to refrain from distributing, marketing or selling in the United States, LifeScan test strips intended for overseas markets. *Id.* LifeScan alleged that, notwithstanding the 2013 agreement, Adelphia had continued to engage in gray-market sales of the test strips. The dispute was resolved with Judge Dearie ordering Adelphia permanently enjoined from selling LifeScan OneTouch Ultra test strips that were not meant for sale in the United States. Potter Decl. Ex. 11.

- Adelphia's President, Yudah ("Lenny") Neuman, was only recently released from prison following a conviction on fraud charges. Neuman pled guilty to attempt and conspiracy to commit mail fraud in connection with a stranger-originated life insurance scam. He was sentenced to a year and a day in prison and ordered to forfeit $300,000. Potter Decl. Ex. 12.

E. Defendants' Sale of Foreign Test Strips in the United States Undermines Abbott's Quality Control Measures.

Diverted FreeStyle test strips seriously undermine Abbott's product quality and present a threat to patient health. Abbott is unable to track international FreeStyle test strips that are diverted into the United States. Gillis Decl. ¶ 10; Kelley Decl. ¶ 9.

Recall notices are only sent to the countries where the recalled product was authorized for sale. Kelley Decl. ¶ 8. American consumers of diverted test strips may not receive notice of a recall affecting that lot of test strips; or Abbott may not be able to identify the consumer and provide that person with any information that may affect the usage, efficacy, or safety of the test strips. *Id.* ¶¶ 8-10; Gillis Decl. ¶¶ 9-10. The diversion of these test strips undermines Abbott's ability to disseminate important information about particular lot numbers and ensure that recall efforts are complete. *Id.*

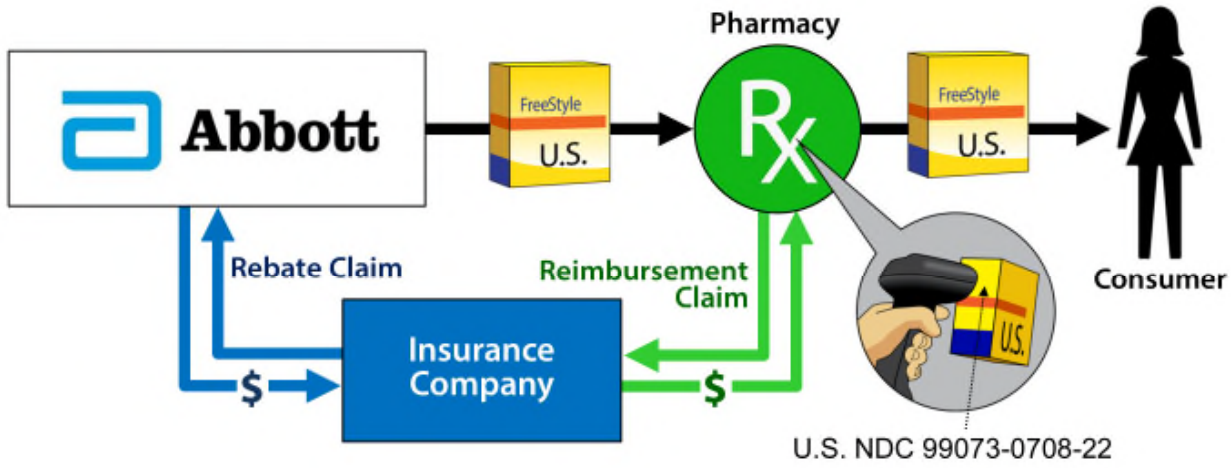
While many consumers may not be immediately aware that they are in possession of diverted international test strips, a growing number of them have contacted Abbott's U.S. call center with questions or complaints concerning diverted international test strips. Gillis Decl. ¶¶

11-12. This year, Abbott's U.S. call center has seen a significant increase in such consumer calls. The U.S. call center, however, is not authorized, trained, or equipped to provide any specific guidance or instruction concerning the use of international test strips because these products, as packaged, have not been cleared for sale in the United States. *Id.* ¶ 8. Instead, Abbott is limited to providing general guidance and offering to replace the product with a U.S. version. *Id.* ¶ 9.

F. Defendants Are Defrauding Abbott and Third-Party Payors.

In the United States, most patients purchase FreeStyle test strips with a prescription—fewer than 5% of U.S. FreeStyle retail test strips are purchased over-the-counter with cash. Nelson Decl. ¶ 5. Abbott wholesales retail boxes of its FreeStyle test strips at a list price of $72.58, or roughly $1.45 per strip, throughout the United States. *Id.* Consumers with prescriptions are typically eligible to receive insurance coverage for their purchases. *Id.* Insurers, third-party payors, and other large purchasers contract with Abbott about how much they will pay—or be rebated—for FreeStyle test strips. *Id.* ¶ 7.

When a pharmacy dispenses a box of FreeStyle retail test strips to an insured consumer, it scans the U.S. NDC number into the pharmacy's computer terminal. The pharmacy's reimbursement request is simultaneously wired to the patient's insurer, which then reimburses the pharmacy on behalf of the insured patient. In the final step in this process, the insurer claims its contracted-for rebate from Abbott. This process is referred to as "adjudication" and is diagrammed below. *Id.* ¶ 6.



Legal Distribution Chain

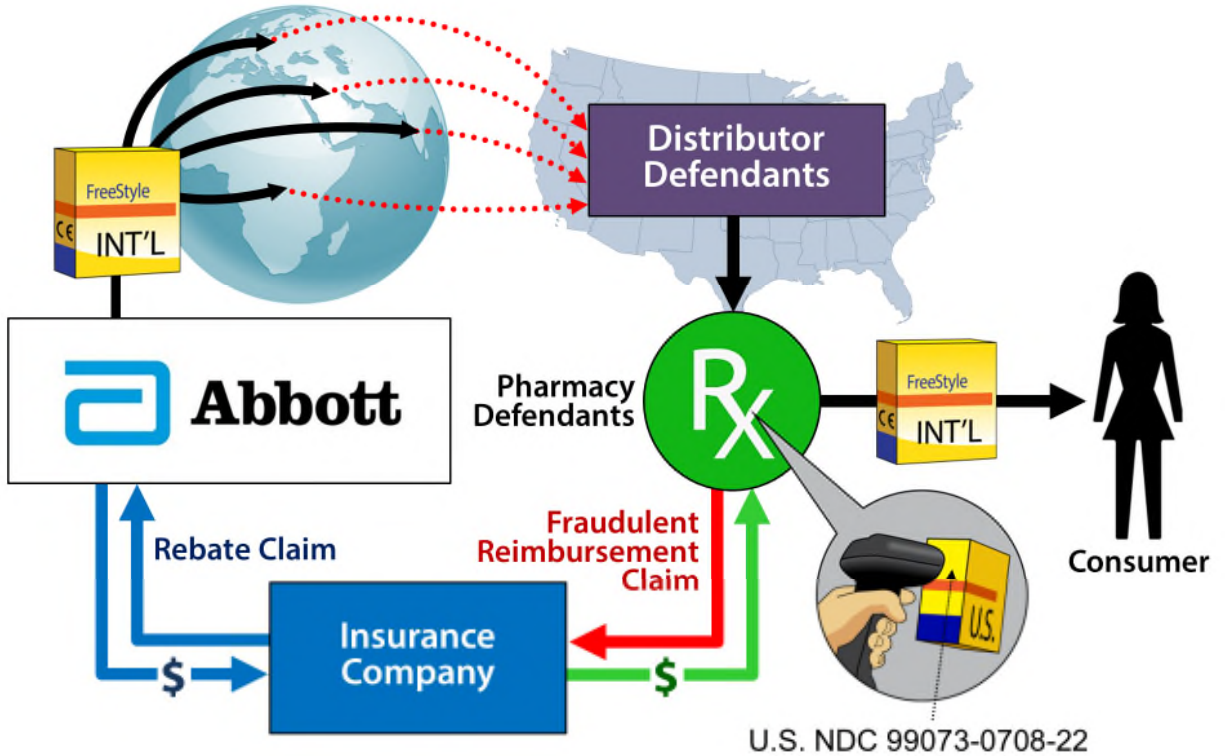
U.S. distributors and pharmacies that buy diverted international test strips acquire them for a lower upfront cost. *Id.* ¶ 9. The average list price for foreign retail FreeStyle test strips is lower than in the United States; and the rebates Abbott pays to foreign insurers are also lower or non-existent. *Id.* After accounting for all reimbursements and rebates, the net price for U.S. and international FreeStyle test strips is similar throughout the developed world. *Id.*

The FreeStyle NDC number is central to the adjudication process. To receive a reimbursement for FreeStyle test strips, a U.S. pharmacy must adjudicate the correct NDC number. *Id.* ¶ 11. Insurers will not reimburse pharmacies for the sale of test strips without a valid NDC number. *Id.* And because approximately 95% of consumers purchase their FreeStyle test strips through insurance, U.S. pharmacies seek reimbursement for almost all sales of FreeStyle test strips.

The Defendants divert FreeStyle test strips into the United States so that pharmacies can sell them at the higher U.S. list price and then fraudulently seek "reimbursement" as if they sold a box of U.S. retail test strips. Diverted international FreeStyle test strips do not have an NDC number. Sterlin Decl. ¶ 6. Accordingly, to recover "reimbursement" payments, the pharmacy

scans a valid NDC number from a box of U.S. retail FreeStyle test strips, but dispenses a box of diverted international FreeStyle test strips to the consumer. The consumer still pays the same amount as if he or she were receiving a box of FDA-cleared test strips, but receives a product that is not approved for sale in the United States. And the insurance company is defrauded of its reimbursement funds. Nelson Decl. ¶¶ 8-15; Declaration of Mark Fishstein dated October 2, 2015 ("Fishstein Decl.") ¶¶ 2-6.

The Defendants' fraud is then passed on to Abbott. Just like the insurance companies, Abbott does not provide rebate payments unless the pharmacies adjudicate a valid NDC number. When a pharmacy supplies a fraudulent NDC number to an insurance company, Abbott then pays a rebate to the insurer based on the same fraudulent NDC number. This process is depicted in the graphic below:



Illegal Distribution Chain

Abbott suffers a net loss for each box of international FreeStyle test strips that is diverted and sold in the United States. Abbott receives the lower list price for the foreign retail box of test strips. Abbott pays a rebate that it is not supposed to pay. And every sale damages Abbott's FreeStyle brand and goodwill. Nelson Decl. ¶¶ 14, 20.

III. ARGUMENT

A. Abbott is Entitled to a Temporary Restraining Order and a Preliminary Injunction Barring Defendants From Selling Infringing Blood Glucose Test Strips.

Defendants' sale of diverted international test strips in the United States violates Abbott's trademark rights under the Lanham Act, 15 U.S.C. §§ 1114(1) and 1125(a), as well as state law, and should be enjoined. Abbott seeks a temporary restraining order and a preliminary injunction barring Defendants from making these illegal—indeed, criminal—sales.[3] "Courts in the Second Circuit have routinely recognized that injunctive relief is appropriate to remedy violations of the Lanham Act." *Bel Canto Design, Ltd. v. MSS HiFi, Inc.*, 837 F. Supp. 2d 208, 219 (S.D.N.Y. 2011).

A plaintiff is entitled to injunctive relief if it can show (a) (1) a likelihood of success on the merits of its claims or (2) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly toward the party requesting the preliminary relief; and (b) irreparable harm. *Zino Davidoff SA v. CVS Corp.*, 571 F.3d 238, 242 (2d Cir. 2009); *Moose Toys Pty, Ltd. v. Thriftway Hylan Blvd. Drug Corp.*, No. 15-CV-4483, 2015 U.S. Dist. LEXIS 105912, at *5 (E.D.N.Y. Aug. 6, 2015) ("Within the

[3] Abbott's counsel sent by FedEx First Overnight a letter to each defendant named in the complaint to this case, notifying them that Abbott would be appearing before the Court on October 9, 2015, to move for an Order to Show Cause with a Temporary Restraining Order and Preliminary Injunction, and providing them with copies of Abbott's Complaint, Proposed Order to Show Cause, Memorandum of Law in Support of Abbott's Request for Order to Show Cause, and other materials being filed in support of Abbott's motion. Potter Decl. ¶ 2 & Ex. 1.

Second Circuit, the standards for the entry of a TRO are the same as those that govern the entry of a preliminary injunction . . . ."). Abbott easily meets that standard and is therefore entitled to injunctive relief.

B. Abbott Is Likely to Succeed on the Merits of its Trademark Claims.

To prevail on its trademark infringement claim, Abbott must show that it has legally protectable trademarks and that Defendants' use of the trademarks is causing a likelihood of confusion among customers. *PepsiCo, Inc. v. F & H Kosher Supermarket, Inc.*, 11-CV-0425, 2011 U.S. Dist. LEXIS 143331 (E.D.N.Y. Aug. 26, 2011), *adopted by* 2011 U.S. Dist. LEXIS 142430 (E.D.N.Y. Dec. 12, 2011). Abbott has made that showing.

1. Abbott owns the FreeStyle Marks.

Abbott owns the FreeStyle Marks, which are valid, protectable trademarks. Potter Decl. ¶ 3 & Ex. 2. The certificates of registration accompanying this submission are "prima facie evidence that the mark[s] are registered and valid (*i.e.*, protectible), that [Abbott] owns the mark[s], and that [Abbott] has the exclusive right to use the mark[s] in commerce." *Lane Capital Mgmt., Inc. v. Lane Capital Mgmt., Inc.*, 192 F.3d 337, 345 (2d Cir. 1999).

2. Defendants' sale of diverted gray market goods is likely to cause confusion.

In ordinary trademark infringement cases, likelihood of confusion is measured by the multi-factor test articulated in *Polaroid Corp. v. Polarad Elec. Corp.*, 287 F.2d 492 (2d Cir. 1961). However, the *Polaroid* test presumes the existence of two entities using two similar, but not identical, marks and thus is "inapplicable" in a gray goods[4] case. *Novartis Animal Health US, Inc. v. LM Connelly & Sons, Pty. Ltd*, 04 Civ 10213, 2005 U.S. Dist. LEXIS 18062, at *9

[4] "A gray-market good is a foreign-manufactured good, bearing a valid United States trademark, that is imported without the consent of the United States trademark holder." *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 285 (1988).

n.13 (S.D.N.Y. Jun. 14, 2005); *see also Novartis Animal Health US, Inc. v. Abbeyvet Export Ltd.*, 409 F. Supp. 2d 264, 266 (S.D.N.Y. 2005) (finding the *Polaroid* test "not useful in the context of gray market goods, since such goods typically utilize the exact same marks, sold in the original packaging legitimately obtained from the manufacturer"); *Prince of Peace Enters. v. Top Quality Food Market, LLC*, 07 Civ. 00349 (RJH), 2007 U.S. Dist. LEXIS 16391, at *12 (S.D.N.Y. Mar. 7, 2007) (same); *see also Original Appalachian Artworks, Inc. v. Granada Electronics, Inc.*, 816 F.2d 68, 74 (2d Cir. 1987) (Cardamone, J., concurring) (stating that the traditional consumer confusion test is "difficult to apply" in gray good cases).

Therefore, courts apply a different standard in gray goods cases, finding a likelihood of consumer confusion exists if the goods (1) were not intended to be sold in the United States and (2) are materially different than the goods authorized for sale in the United States. *Original Appalachian Artworks, Inc.*, 816 F.2d at 71-73; *Abbeyvet*, 409 F. Supp. 2d at 266.

The reason for the material difference standard is not that consumers will be confused about the origin of the gray good products, but that as a result of their sale, "the public is likely to become confused or deceived as to which characteristics are properly associated with the trademark" leading to a possible erosion of the goodwill associated with the mark. *Dan-Foam A/S & Tempur-Pedic, Inc. v. Brand Name Beds, LLC*, 500 F. Supp. 2d 296, 312 (S.D.N.Y. 2007) (quoting *Bordeau Bros., Inc. v. Int'l Trade Comm'n*, 444 F.3d 1317, 1320 (Fed. Cir. 2006)); *see also Zip Int'l Group, LLC v. Trilini Imports, Inc.*, 09-CV-2437 (JG)(VVP), 2010 U.S. Dist. LEXIS 15368, at *10 (E.D.N.Y. Feb. 22, 2010) ("[C]onsumers may unwittingly purchase the goods on the basis of the domestic markholder's reputation only to be disappointed when the

product does not meet their expectations.").[5] Even if the quality of the gray good product is arguably equal to the mark-holder's authorized domestic product, if the two are materially different, the former is infringing because it "may still deprive the registrant of his ability to shape the contours of his reputation." *Societe Des Produits Nestle v. Casa Helvetia*, 982 F.2d 633, 636 (1st Cir. 1992).

a. Diverted international test strips are not intended for sale in the United States.

The diverted international FreeStyle test strips sold by Defendants are not authorized or intended for sale in the United States. *See generally* Sterlin Decl. Unlike Abbott's authorized domestic test strips, the diverted international test strips are not labeled to meet U.S. regulatory requirements and are not in fact sold by Abbott to U.S. customers. *Id.* Rather, the diverted international test strips are specifically packaged to meet regulatory requirements of the particular country in which they are intended for sale. *See Abbeyvet*, 409 F. Supp. 2d at 266 (finding defendant's goods not intended for sale in the United States because "the product inserts and packaging design [were] specifically tailored for use in the U.K. and designed to meet U.K. regulatory requirements"); *see, e.g.*, Kneir Decl. ¶¶ 12 & 15; Exs. 3 & 6 (showing product labeled "For Sale in India only").

b. The diverted international test strips Defendants sold are materially different from Abbott's authorized domestic product in numerous ways.

In analyzing whether a diverted international product is materially different from an authorized domestic product, courts in the Second Circuit "apply a low threshold of materiality." *Zino Davidoff*, 571 F.3d at 246. This standard requires "no more than a slight difference which

[5] This standard does not require a trademark holder to demonstrate any actual confusion. *See Bel-Canto*, 837 F. Supp. 2d at 231 (citing *Lois Sportswear, USA, Inc. v. Levi Strauss & Co.*, 799 F.2d 867, 875 (2d Cir. 1986)).

consumers would likely deem relevant when considering a purchase of the product." *Id.* The materiality standard is low because "[t]he probability of confusion is great . . . when the same mark is displayed on goods that are not identical but that nonetheless bear strong similarities in appearance or function." *Nestle*, 982 F.2d at 641. Subtle differences may not be enough to alert a user that he has purchased a diverted product, but can certainly affect a user's perception of the authorized product and lead to confusion. *Id.* ("[I]t is by subtle differences that consumers are most easily confused."); *LM Connelly*, 2005 U.S. Dist. LEXIS 15214, at *14 (same). In this case, there are numerous subtle but important differences between the diverted international test strips sold by Defendants and Abbott's authorized domestic products—differences that consumers would unquestionably find material and which imperil the goodwill associated with the FreeStyle Marks.

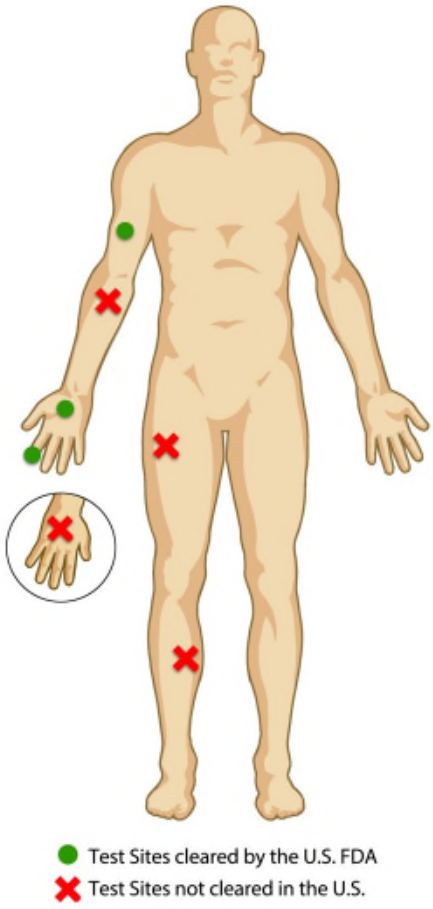
i. Labeling differences

The diverted international test strips make claims that have been specifically rejected by the FDA. As a result, they are "misbranded" medical devices under the Federal Food, Drug and Cosmetics Act and their sale in the United States is a ***criminal*** offense. 21 U.S.C. §§ 331, 333, 352. For this reason alone, these diverted international test strips are materially different from Abbott's authorized domestic test strips, and their sale should be enjoined.

When performing a blood glucose test, the user must obtain a blood drop from a "test site" on his or her body. Many consumers test their glucose levels multiple times per day and therefore would like to be able to use a number of different testing sites rather than constantly obtaining blood from a single location. Sterlin Decl. ¶ 10. Therefore, Abbott sought approval from the FDA to indicate that consumers could use FreeStyle brand test strips to test blood sampled from any of seven different sites: finger; upper arm; palm; hand; forearm; calf; and

thigh. *Id.* ¶ 11. In support of this application, Abbott submitted data to support the accuracy of blood testing from each site. *Id.* The FDA concluded that the testing performed on the forearm, hand, calf, and thigh was outside of the acceptable range for regulatory approval. *Id.* Therefore, the FDA has only approved three testing sites for FreeStyle test strips sold in the United States: finger; upper arm; and palm. *Id.*

Regulatory bodies in different countries, however, apply different standards. Internationally, FreeStyle test strips are approved for forearm, full hand, calf, and thigh testing. Sterlin Decl. ¶12. Accordingly, international FreeStyle test strips are packaged with guidance and instructions for testing at a broader range of sites than U.S. test strips. *Id.* ¶ 12. Thus, any international FreeStyle test strips that are distributed in the United States would indicate testing sites that are not cleared—and were specifically disallowed—by the FDA in the United States.



By selling test strips that feature indications expressly rejected by the FDA, Defendants are engaged in criminal conduct. *See generally United States v. Scully*, 14-CR-208, 2015 U.S. Dist. LEXIS 73831 (E.D.N.Y. Jun. 8, 2015) (criminal prosecution for importation of foreign version of U.S. drugs lacking "Rx only" warning or English on label). Congress outlawed the "introduction" or "receipt in interstate commerce of any . . . device . . . that is . . . misbranded." 21 U.S.C. § 331. This offense is punishable by up to a year in prison, or up to three years' imprisonment when committed with the intent to defraud or mislead. *Id.* § 333(a). A medical device is "misbranded" if it is "false or misleading in any particular" or if its labeling does not offer "adequate directions for use." *Id.* § 352(a), (f). The term "adequate directions for use" is defined by regulation as "directions under which the layman can use a device safely and for the

purposes for which it is intended," and directions can be inadequate if they include an "incorrect specification of" the device's "method of administration." 21 C.F.R. § 801.5(f). Here, the diverted international test strips falsely and misleadingly suggest that they are indicated for testing from the forearm, back of hand, calf, and thigh in the United States. For the same reason, they fail to provide "adequate directions for use" per 21 U.S.C. § 352(f) because they provide an "incorrect specification of" the "method of administration" approved by the FDA. 21 C.F.R. § 801.5(f); *Scully*, 2015 U.S. Dist. LEXIS 73831 (finding that violation of FDA regulations can be the basis for criminal liability under 21 U.S.C. § 331). Thus, Defendants' sale of these diverted international test strips is a criminal act; a fact that consumers would undoubtedly find material.

Courts have repeatedly found that diverted goods that violate FDA labeling requirements are materially different than authorized domestic goods. For example, Judge Hurley found a material difference between diverted Canadian hair products and authorized U.S. versions based on the former's lack of FDA-required labeling concerning ingredients and product weight. *Helene Curtis, Inc. v. Nat'l Wholesale Liquidators*, 890 F. Supp. 152, 159 (E.D.N.Y. 1995). Similarly, Judge Carter (in a recommendation adopted by Judge Mauskopf) found that failure to comply with FDA labeling standards rendered diverted bottles of Pepsi materially different than Pepsico's authorized domestic soda. *F&H Kosher Supermarket*, 2011 U.S. Dist. LEXIS 143331, at *14.[6] Certainly, making a claim that the FDA has *specifically rejected* regarding a medical device would constitute a material difference. A consumer seeing the diverted international

[6] *See also Prince of Peace*, 2007 U.S. Dist. LEXIS 16391, at *17 (herbal supplements); *PepsiCo, Inc. v. Reyes*, 70 F. Supp. 2d 1057, 1059 (C.D. Cal. 1999) (soda); *Grupo Gamesa S.A. v. Dulceria El Molino Inc.*, 39 U.S.P.Q.2d 1531, 1533 (C.D. Cal. 1996) (cookies and crackers); *Ferrero USA, Inc. v. Ozak Trading, Inc.*, 753 F. Supp. 1240, 1244 & 1247 (D.N.J. 1991), *aff'd by* 19 U.S.P.Q.2D (BNA) 1468 (3d Cir. 1991) (breath mints). *Cf. Clairol, Inc. v. Boston Discount Center, Inc.*, 608 F.2d 1114, 1121 (6th Cir. 1979) (finding sale of diverted hair dye to be unfair competition under state law for failure to include FDA-required warning).

product sold by Defendants will likely be confused regarding whether he should use alternate blood testing sites, which may diminish the consumer's opinion of the quality of FreeStyle test strips and devalue the FreeStyle Marks.

Furthermore, the outer box of international FreeStyle test strips does not provide several written warnings and instructions featured on the U.S. retail box, including "Do not reuse" and "For *in vitro* diagnostic use." *Id.* ¶ 24. "[T]he fact that the packaging for the [diverted goods] do[es] not contain various warnings to the consumer that are listed on Plaintiff's packaging is also materially significant." *Johnson & Johnson Consumer Cos. v. Aini*, 540 F. Supp. 2d 374, 387 (E.D.N.Y. 2008).

ii. Lack of an NDC Number

The diverted international test strips are not approved for sale in the United States and therefore do not contain an NDC number. Sterlin Decl. ¶ 6. This alone may be material to a reasonable consumer. *See Abbeyvet*, 409 F. Supp. 2d at 267 (finding fact that diverted good "has not been approved for sale or use in the United States by the Food and Drug Administration" would likely be material to consumers). Moreover, consumers would certainly find it material that the diverted international test strips are not actually subject to reimbursement from their insurers and are reimbursed only as the result of an intentional fraud committed by pharmacies. Nelson Decl. ¶¶ 8-15. *See Original Appalachian*, 816 F.2d at 73 (inability to register "adoption" papers for diverted Cabbage Patch dolls was a material difference). *Cf. Nestle*, 982 F.2d at 644 ("Price, without doubt, is also a variable with which purchasers are concerned.").

iii. Language differences on packaging

Another material difference found on many of the boxes sold by Defendants is the use of additional languages not used on Abbott's authorized domestic test strips. Consistent with FDA's requirements, all FreeStyle test strips intended for distribution in the United States are

accompanied by instructional inserts written in English and Spanish. Sterlin Decl. ¶ 16. Many FreeStyle test strips that are manufactured for sale internationally contain instructional inserts featuring various languages other than English or Spanish. *Id.* ¶ 16 & Exs. 11 & 14.

Courts have long recognized that the use of additional languages not on the authorized domestic product is likely to cause consumer confusion. In *Original Appalachian Artworks*, the Second Circuit found that the use of a foreign language on the "adoption papers and birth certificate[s]" of gray market Cabbage Patch Dolls "create[d] confusion over the source of the product and result[ed] in a loss of [plaintiffs'] good will." 816 F.2d at 73.[7] The same is also true here. *See also F&H Kosher Supermarket*, 2011 U.S. Dist. LEXIS 143331 at *14 (Hebrew on Pepsi bottles constituted material difference); *Reyes*, 70 F. Supp. 2d at 1059 (Spanish on Pepsi bottles constituted material difference); *Fender Musical Instruments Corp. v. Unlimited Music Ctr., Inc.*, 3:93CV2449, 1995 U.S. Dist. LEXIS 15746, at *9-10 (D. Conn. Feb. 16, 1995) (Japanese in owner's manual for guitars constituted material difference).

iv. Different units of measurement

Many of the diverted international test strips Defendants sell also differ from authorized domestic FreeStyle test strips because they use units of measurement that are foreign or unfamiliar to most American consumers. Sterlin Decl. ¶ 20. The FDA requires that U.S. products use U.S. measurements, including degrees Fahrenheit, milligrams, and deciliters. *Id.* However, various regions around the world use other units of measurement, including degrees Centigrade and millimoles. *See, e.g.*, Sterlin Decl. Ex. 16. The handling and use instructions for FreeStyle test strips that are intended for distribution in these regions use metric and degrees

[7] Some courts have even held that the use of foreign spellings of English words constitutes a material difference. *See, e.g., Bayer Healthcare LLC v. Nagrom, Inc.*, No. 03-CV-2448, 2004 U.S. Dist. LEXIS 19454, *13 (D. Kan. Sept. 7, 2004) (citing *Ferrero U.S.A., Inc.*, 753 F. Supp. at 1244, 1247).

Centigrade measurements. Consumers might be put off by these unfamiliar units of measurement or have difficulty converting them to units they are accustomed to dealing with, thereby negatively affecting consumer perception of Abbott and the FreeStyle Marks. *See Abbeyvet*, 409 F. Supp. 2d at 267 (discussing "negative reaction" to the brand when "consumer finds it difficult to calculate the right dosage in metric units"). More importantly, foreign units of measurement endanger patients by impairing their ability to achieve accurate test results or otherwise understand proper testing, handling, and storage conditions. *See LM Connelly*, 2005 U.S. Dist. LEXIS 18062, at *15 (noting that purchaser of gray-market pet medicine "could give his pet an improper dose if confused between pounds and kilograms").

v. **Lack of a U.S. toll-free number**

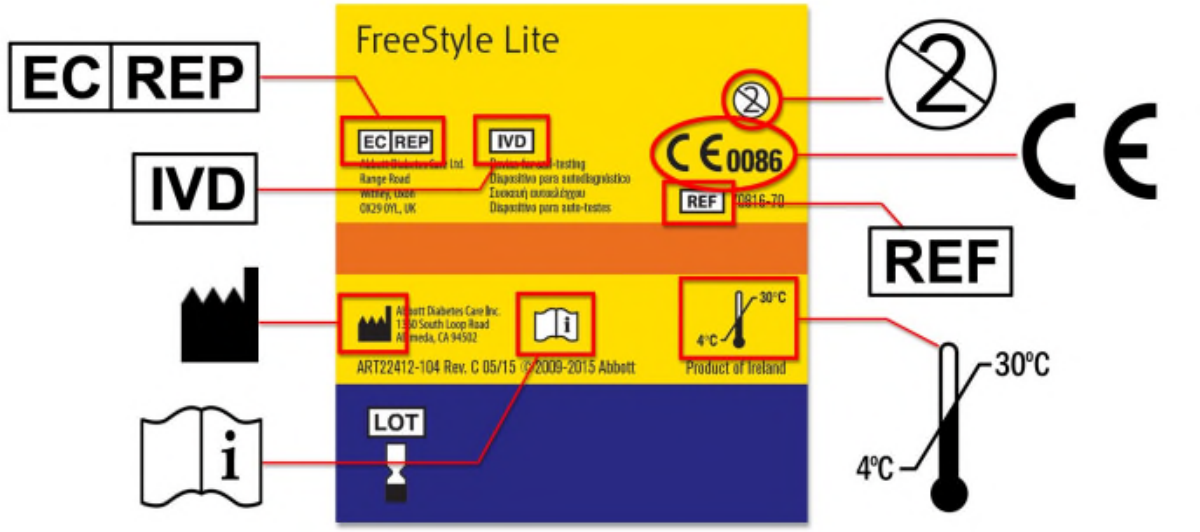
All packages of FreeStyle test strips intended for sale in the United States list the U.S. call center's toll-free number. Sterlin Decl. ¶ 14. Packages of FreeStyle test strips intended for international sale do not—they have the phone number for the country's call center where the product is intended to be sold. *Id.* These phone numbers are not generally accessible from the United States, meaning that U.S. customers who purchase these diverted products may find themselves unable to seek guidance from Abbott about the safe and proper use of their test strips. *Id.* This obstacle to customer support undoubtedly could lead to consumer confusion and the tarnishment of Abbott's reputation and goodwill. *See, e.g.*, *LM Connelly*, 2005 U.S. Dist. LEXIS 18062, at *14 (finding material difference because diverted product listed a foreign emergency contact number); *Bayer Corp v. Custom School Frames, LLC*, 259 F. Supp. 2d 503, 506-07 (E.D. La. 2003) (same).

Even if a U.S. consumer manages to find the U.S. toll-free number despite the foreign number listed on the box, Abbott's U.S. call center is only approved and equipped to

troubleshoot usage problems for the U.S. version of the product. Gillis Decl. ¶ 8. For example, a consumer who has purchased diverted international test strips might read the instructional insert indicating that the product can be used to test blood drawn from his calf and call the U.S. call center inquiring about doing so. The U.S. call center would be unable to provide guidance for that test site, since this would constitute an off-label use of the U.S. product. *Id.* This divergence in the level of service available for the domestic and the diverted international product constitutes a further material difference. *See Original Appalachian*, 816 F.2d at 73 (inability to register "adoption" papers for diverted Cabbage Patch dolls was a material difference); *Bel Canto*, 837 F. Supp. 2d at 231 (lack of warranty for diverted goods was a material difference); *Fender*, 1995 U.S. Dist. LEXIS 15746 at *9-10 (same).

vi. Use of symbols in place of text

FDA does not generally approve the use of symbols on packaging for home-use products unless the symbols are accompanied by adequate explanatory text. Sterlin Decl. ¶ 18. FDA has published guidance instructing manufacturers, including Abbott, not to use symbols for products like FreeStyle test strips. Sterlin Decl. Ex. 15. The vast majority of diverted international FreeStyle test strips are packaged in cartons and with instructions that bear various symbols concerning, among other things, the manufacturer, expiration date, and storage temperature limitations, as shown in the image below. Sterlin Decl. ¶ 19.



Many of these symbols are unfamiliar to U.S. consumers. The sale of these international FreeStyle test strips in the United States not only violates the FDA's guidance against symbols, but could confuse or fail to inform consumers about the proper use, handling, and storage of the test strips. This may potentially cause misuse or mishandling by U.S. consumers. Sterlin Decl. ¶ 19.

c. Abbott is also likely to prevail on its Lanham Act claims because Defendants are subverting Abbott's quality-control measures.

In addition, Abbott is likely to prevail on its Lanham Act claims because Defendants are undermining Abbott's quality-control measures. Kelley Decl. ¶10. The Second Circuit has recognized that "[o]ne of the most valuable and important protections afforded by the Lanham Act is the right to control the quality of the goods manufactured and sold under the holder's trademark." *El Greco Leather Prods. Co. v. Shoe World, Inc.*, 806 F.2d 392, 395 (2d Cir. 1986). A defendant who interferes with a trademark owner's quality-control measures "subjects the trademark holder to the risk of injury to the reputation of its mark." *Zino Davidoff*, 571 F.3d at

243.[8] A diverted good that does not meet the trademark owner's quality-control standards "is deemed for Lanham Act purposes not to be the genuine product of the holder, and its distribution constitutes trademark infringement." *Warner-Lambert Co. v. Northside Dev. Corp.*, 86 F.3d 3, 6 (2d Cir. 1996).

Therefore, "a trademark holder is entitled to an injunction against one who would subvert its quality control measures" if it can make a three-part showing: (1) that it has established, legitimate, substantial, and non-pretextual quality control measures; (2) that it abides by these procedures, and (iii) sales of products that fail to conform to these procedures will diminish the value of the mark. *Zino Davidoff*, 571 F.3d at 244.

Abbott has shown that it is likely to prevail under this theory as well. Abbott produces FreeStyle test strips in batches and imprints each batch with a lot number. Kelly Decl. ¶¶ 4-5. Abbott monitors the quality of FreeStyle test strips globally and tracks issues and complaints by lot number. *Id.* Abbott uses lot numbers to monitor which lot of test strips was sold in which country. *Id.* Because of these quality-control efforts, if Abbott identifies an issue with a particular batch of test strips, it can make a targeted recall of the affected lot, rather than having to pull all of its product off the market. *Id.* ¶¶ 6-9. This is preferable from a quality assurance and public safety standpoint because a "market-wide" recall can confuse consumers, cause them to dispose of unaffected test strips or forgo blood testing, or otherwise endanger the very patients that the recall was designed to protect. *Id.* ¶ 8.

If an issue is identified with a particular batch of test strips, Abbott can direct its resources to educating pharmacies and consumers in the country where that batch was sold or, if

[8] When a defendant interferes with the trademark holder's quality-control procedures, "the actual quality of the goods is irrelevant; it is the *control* of quality that a trademark holder is entitled to maintain." *Zino Davidoff*, 571 F.3d at 246 (quoting *El Greco*, 806 F.2d at 395) (emphasis added).

necessary, notify that market of the need for a recall. *Id.* Not only is this method efficient, but it also ensures that recall efforts are effective. If Abbott notified every pharmacy worldwide whenever a potential issue arises in a particular market, it would quickly develop a reputation like the proverbial boy who cried wolf: pharmacists and patients would be unlikely to pay attention to warnings and recall notices if they were frequently peppered with warnings about lot numbers that were only available thousands of miles away from them. *Id.*

Defendants' diversion of foreign test strips undermines these important quality-control measures and makes it more difficult for Abbott to remediate problems with particular test strip lots. If Abbott identifies an issue with a particular batch of test strips, its quality-control system allows it to take targeted action in the country to which that particular batch was sold. However, Defendants' diversion thwarts Abbott's targeted remediation efforts and leaves U.S. consumers at risk of receiving recalled product.

In *Zino Davidoff*, the Second Circuit recognized the importance of quality-control measures like those employed by Abbott. 571 F.3d at 243-46. In that case, the district court granted a preliminary injunction barring a retailer from selling bottles of diverted cologne from which the manufacturer's unique product code ("UPC") had been removed. *Id.* at 241-42. On appeal, the Second Circuit noted that when quality issues arose, the UPC "permit[ted] easy, rapid identification of affected product" and "facilitate[d] a targeted recall that will remove the defective goods from the channels of commerce while leaving unaffected goods in place." *Id.* at 245. The UPC thus helped the manufacturer detect counterfeits, identify defective products, and remediate problems via effective (i.e., "small and targeted") recalls. *Id.* at 244-45; *see also Aini*, 540 F. Supp. 2d at 386 ("[B]atch codes are an important means for manufacturers to control the quality of their products."). Because the defendant's sales undermined those objectives, the

Second Circuit affirmed the district court's grant of a preliminary injunction. *Zino Davidoff*, 571 F.3d at 244-45. The same is true in this case: by diverting test strips out of their intended market, Defendants thwart Abbott's efforts to address product defects with effective recalls that are "small and targeted." *Id.* Defendants' acts thus constitute trademark infringement. *See id.*; *see also Bel Canto*, 837 F. Supp. 2d at 232 (finding that alteration of serial numbers thwarted trademark holder's efforts to make a "targeted recall" and constituted trademark infringement).

In *F&H Kosher Supermarket*, the court found infringement under a quality-control test where diversion of Israeli Pepsi prevented plaintiff from "rotating stale, damaged or substandard quality" soda off retail shelves. 2011 U.S. Dist. LEXIS 143331 at *12. Certainly, if product diversion that subverts Pepsi's efforts to keep flat soda off of retail shelves constitutes infringement, so too does diversion that potentially exposes U.S. consumers to recalled medical devices.

d. Abbott is also likely to prevail on its state law claims that Defendants are diluting the FreeStyle Marks.

Abbott is also entitled to an injunction pursuant to the New York anti-dilution law, N.Y. Gen. Bus. Law § 360-*l*. This statute requires a plaintiff to "demonstrate ownership of a distinctive mark and the likelihood of dilution of that mark." *F&H Kosher Supermarket*, 2011 U.S. Dist. LEXIS 143331, at *18 (citing *The Sports Auth., Inc. v. Prime Hospitality Corp.*, 89 F.3d 955, 966 (2d Cir. 1996)). Dilution occurs when a defendant sells an inferior product under plaintiff's mark—known as tarnishment. *Perkins School for the Blind v. Maxi-Aids, Inc.*, 274 F. Supp. 2d 319, 325 (E.D.N.Y. 2003).

As noted above, Abbott owns the FreeStyle Marks, which are strong, famous, registered trademarks that Abbott has used for many years and spent many millions of dollars to promote. Potter Decl. ¶ 3 & Ex. 2; Nelson Decl. ¶¶ 3-4, 16-20. Defendants' recent sales of

diverted international test strips are diluting those marks through tarnishment—associating Abbott's distinctive marks with a mislabeled product that is likely to confuse consumers and which fails to give them the instructions and customer support to which FreeStyle users are accustomed. *See* section III.B.2.b, *supra.* By selling such a product bearing Abbott's trademarks, Defendants have diluted the marks and should therefore be enjoined. *See F&H Kosher Supermarket*, 2011 U.S. Dist. LEXIS 143331, at *18 (finding dilution under section 360-*l* based on sale of diverted soda); *Perkins*, 274 F. Supp. 2d at 326 (finding section 360-*l* claim adequately pled where plaintiff alleged that defendants sold diverted international product with inferior warranty).

C. At a Minimum, Abbott Has Presented Serious Questions Going to the Merits and the Balance of Hardships Decidedly Favors Abbott.

Even if the Court finds that Abbott has not demonstrated that it is likely to succeed on the merits of its Lanham Act claims, for the reasons noted above, there are at least "sufficiently serious questions going to the merits to make them a fair ground for litigation" and "a balance of hardships tipping decidedly toward the party requesting the preliminary relief." *Zino Davidoff*, 571 F.3d at 242 (citation omitted). As discussed in greater detail below, *infra* section III.D, the Defendants' continuing conduct is irreparably harming Abbott and subjecting it to potential loss of control over its valuable trademarks. *See F&H Kosher Supermarket*, 2011 U.S. Dist. LEXIS 143331 at *21.

In contrast, the proposed injunction would simply prevent Defendants from doing what federal criminal law already forbids—selling misbranded medical devices. 21 U.S.C. §§ 331, 333, 352(f). Defendants can hardly claim any hardship in being enjoined from making illegal sales of a product that confuses consumers and exists in the U.S. market primarily to defraud insurers and Abbott. Nelson Decl. ¶¶ 8-15; *see Mitchell Group USA LLC v. Udeh*, 14-cv-5745,

2015 U.S. Dist. LEXIS 18801, at *8 (E.D.N.Y. Feb. 17, 2015) ("[H]ardship to a defendant based on his or her own wrongful acts is not legally cognizable."); *Philip Morris USA Inc. v. 5 Bros. Grocery Corp.*, 13-CV-2451, 2014 U.S. Dist. LEXIS 112274, at *13 (E.D.N.Y. Aug. 5, 2014) ("Absent an injunction, there will be further erosion of plaintiff's good will and reputation. Defendants, on the other hand, will be called upon to do no more than refrain from what they have no right to do in the first place.").

D. Defendants Are Causing Irreparable Harm to Abbott.

Where, as here, a Lanham Act plaintiff has succeeded in showing a likelihood of confusion, irreparable injury "almost inevitably follows." *Omega Importing Corp. v. Petri-Kine Camera Co.*, 451 F.2d 1190, 1195 (2d Cir. 1971). A finding of a likelihood of confusion is considered "strong evidence of irreparable harm because damage to reputation is difficult to prove or quantify." *Ahava (USA), Inc. v. J.W.G., Ltd.*, 250 F. Supp. 2d 366, 371 (S.D.N.Y. 2003); *see also VAS Indus. v. New York Sound, L.L.C.*, 06 Civ 3454, 2006 U.S. Dist. LEXIS 41427, at *9 (S.D.N.Y. Jun. 21, 2006). The reason for this is simple: an infringer selling an inferior product destroys goodwill associated with the plaintiff's mark that cannot be recovered or compensated for. *See U.S. Polo Ass'n v. PRL USA Holdings, Inc.*, 800 F. Supp. 2d 515, 541 (S.D.N.Y. 2011), *aff'd* 511 F. App'x 81, 85 (2d Cir. Feb. 11, 2013); 5 J. Thomas McCarthy, McCarthy on Trademarks § 30:47 (4th ed. 2015) ("[O]nce a probability of proving likelihood of confusion . . . is shown, the trademark owner's business goodwill and reputation are at risk. . . . Like trying to un-ring a bell, trying to use dollars to 'compensate' after the fact for damage to business goodwill and reputation cannot constitute fair or full compensation."). The connection between consumer confusion, reputational injury, and irreparable harm is so strong that courts historically *presumed* irreparable harm when likelihood of confusion was shown. *See Zino*

Davidoff, 571 F.3d at 247 (citing *Weight Watchers Int'l Inc. v. Luigino's, Inc.*, 423 F.3d 137, 144 (2d Cir. 2005)).

As demonstrated above, *supra* section III.B.2, Defendants' conduct is likely to cause consumer confusion and tarnish Abbott's invaluable goodwill. Indeed, Abbott has recently seen a marked increase in calls complaining about issues related to diverted international test strips. Gillis Decl. ¶12. Defendants are interfering with Abbott's ability to control its reputation, a harm that is "neither calculable nor precisely compensable," and thus amounts to irreparable harm. *Pretty Girl, Inc. v. Pretty Girl Fashions, Inc.*, 778 F. Supp. 2d 261, 269 (E.D.N.Y. 2011).

E. Other Factors Also Support an Award of Injunctive Relief.

Since the Supreme Court's decision in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006)—a patent case—some courts have concluded that a party seeking injunctive relief must also show that remedies available at law are inadequate to compensate for its injuries, that the balance of hardships between plaintiff and defendant favors granting an injunction, and that the public interest would not be disserved by an injunction. *See F&H Kosher Supermarket*, 2011 U.S. Dist. LEXIS 143331, at *19-20; *U.S. Polo Ass'n*, 800 F. Supp. 2d at 541. These factors also support Abbott's request for injunctive relief.

For the same reason that Abbott is suffering irreparable harm, remedies available at law are inadequate to compensate Abbott for its injuries. *See U.S. Polo Ass'n*, 800 F. Supp. 2d at 541 (noting that adequate remedies and irreparable harm inquiries overlap significantly). Abbott's reputation and the goodwill associated with its trademarks are invaluable and not precisely quantifiable. *See id.* Thus, traditional legal remedies cannot adequately compensate Abbott for its injuries and an injunction is necessary. *See F&H Kosher Supermarket*, 2011 U.S. Dist. LEXIS 143331 at *21 ("If Defendant is allowed to continue to use the PEPSI marks, it may

adversely affect Plaintiff's reputation and business in ways that may be difficult to quantify and that will not lend themselves easily to monetary compensation.").

As noted above, *supra* section III.C, the balance of hardships between Abbott and Defendants favors granting an injunction. The legitimate harm to Abbott's reputation far outweighs whatever effect Defendants would experience from being temporarily barred from their criminal sales of a misbranded product that confuses consumers and exists in the U.S. market primarily to defraud insurers and Abbott. Nelson Decl. ¶¶ 8-15; *see Mitchell Group USA*, 2015 U.S. Dist. LEXIS 18801, *8; *5 Bros. Grocery Corp.*, 2014 U.S. Dist. LEXIS 112274, at *8.

Finally, the public interest would not be disserved by an injunction. Indeed, an injunction would serve the public interest by halting the sale of a misbranded medical device and protecting consumers from confusion. *F&H Kosher Supermarket*, 2011 U.S. Dist. LEXIS 143331 at *21-22; *U.S. Polo Ass'n*, 800 F. Supp. 2d at 541. Unlike some cases where defendants might argue that gray-good sales benefit consumers via lower prices, in this case consumers see no benefit because the strips are almost always paid for by insurers, which pay no less when a pharmacist dispenses gray-market product. Nelson Decl. ¶ 15.

F. Abbott is Entitled to Limited Expedited Discovery.

To halt the irreparable harm Abbott is suffering, it is necessary to cut off the trade in the infringing goods. Therefore, Abbott is also requesting limited expedited discovery, requiring Defendants and non-parties to provide within three business days the name and contact information of their suppliers and customers of diverted international test strips, as well as the quantity purchased and sold.

Federal courts have broad discretion to expedite the normal pace of discovery in cases seeking temporary or preliminary injunctive relief. 28 U.S.C. § 1657 directs that "the court shall expedite the consideration of . . . any action for temporary or preliminary injunctive relief." Rule 26(d) of the Federal Rules of Civil Procedure allows for expedited discovery and an Advisory Committee comment to that rule notes that expedited discovery "will be appropriate in some cases, such as those involving requests for a preliminary injunction." Fed. R. Civ. P. 26(d) and Advisory Comm. Note. Expedited discovery is "routinely granted in actions involving infringement and unfair competition." *Benham Jewelry Corp. v. Aron Basha Corp.*, No. 97 Civ. 3841, 1997 U.S. Dist. LEXIS 15957, at *58 (S.D.N.Y. Oct. 14, 1997). Appropriately tailored expedited discovery is justified by the need to quickly identify other infringers and put an end to their infringing conduct. *See Mitchell Group USA*, 2015 U.S. Dist. LEXIS 18801, at *6 (expedited discovery "confirmed the identities of the distributor and/or suppliers of the [infringing] products"); *Twentieth Century Fox Film Corp. v. Mow Trading Corp.*, 749 F. Supp. 473, 475 (S.D.N.Y. 1990) (expedited discovery "may very well lead to evidence of continuing infringement by this defendant or others").

Courts in this district have applied a "flexible standard of reasonableness and good cause" in deciding whether to grant a party's request for expedited discovery. *North Atl. Operating Co. v. Evergreen Distribs., LLC*, 293 F.R.D. 363, 367 (E.D.N.Y. 2013). In making these determinations, some courts consider whether the requesting party has demonstrated the following factors first outlined in *Notaro v. Koch*, 95 F.R.D. 403, 405 (S.D.N.Y. 1982): "(1) irreparable injury, (2) some probability of success on the merits, (3) some connection between the expedited discovery and the avoidance of the irreparable injury, and (4) some evidence that the injury that will result without expedited discovery looms greater than the injury that the

defendant will suffer if the expedited relief is granted." *Id.*; *cf. New York v. Mt. Tobacco Co.*, 953 F. Supp. 2d 385, 390 (E.D.N.Y. 2013). Abbott's request for expedited discovery easily meets both the reasonableness and the *Notaro* standards.

Abbott's request is reasonable under the circumstances and supported by good cause. It is seeking only to identify others in the distribution chain so that they may be joined in the action and restrained from causing further harm to Abbott and its valuable trademarks. *See Mow Trading Corp.*, 749 F. Supp. at 475. This information can be gathered with minimal effort—likely no more than the click of a button to search a sales database. *See North Atl. Operating Co.*, 293 F.R.D. at 368 (the reasonableness analysis asks whether the requested materials can "physically be gathered on the proposed timeline"). Good cause exists because until Abbott is able to identify the other players in the market for infringing foreign test strips, those entities will continue to irreparably harm Abbott. *See Mow Trading Corp.*, 749 F. Supp. at 475.

Abbott's request for limited expedited discovery is also appropriate under the preliminary injunction-type factors outlined in *Notaro*. As noted above, Abbott has shown that it is being irreparably harmed (*see supra* section III.D) and that it is not just probable, but in fact likely, that it will succeed on its trademark claims (*see supra* section III.B.2).

As to the third *Notaro* factor, the limited expedited discovery Abbott requests—identifying information for Defendants' suppliers of and customers for the infringing foreign test strips—is clearly connected to the irreparable harm Abbott is suffering. Just as Defendants' purchase and sale of the infringing foreign test strips is likely to cause consumer confusion and undermine Abbott's quality-control measures, so too are the purchases and sales of others in the Defendants' supply chain.

Regarding the fourth *Notaro* factor, without expedition, Abbott will continue to be harmed and the public will be subject to continued likelihood of confusion by each and every additional sale of infringing product made by Defendants' suppliers and customers. In contrast, Defendants will suffer no harm in having to disclose sooner rather than later their suppliers of and customers for the infringing international test strips. This information is easy for Defendants to retrieve within the proposed timeframe and is clearly within the range of permissible discovery.

IV. CONCLUSION

For the above-stated reasons, the Court should grant Abbott's request for a temporary restraining order, expedited discovery, and a preliminary injunction, and should award any other and further relief that the Court may deem just and proper.

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Respectfully submitted,
PATTERSON BELKNAP WEBB & TYLER LLP

By: 

Geoffrey Potter
gpotter@pbwt.com
Aron Fischer
afischer@pbwt.com
Jeremy A. Weinberg
jweinberg@pbwt.com
R. James Madigan III
jmadigan@pbwt.com
Matthew Funk
mfunk@pbwt.com

1133 Avenue of the Americas
New York, NY 10036-6710
Tel: (212) 336-2000
Fax: (212) 336-2222

Attorneys for Plaintiffs Abbott Laboratories, Abbott Diabetes Care Inc., and Abbott Diabetes Care Sales Corporation